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CAS MEDICAL SYSTEMS, INC.
TECHNOLOGY APPLIED TO MEDICINE
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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

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Contact: Ron Jeffrey – Director, Regulatory Affairs
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Prepared: July 11, 2005

Trade Name: CAS 750E Series Monitor

Common Name: Multi-Function Patient Monitor

Classification Name: Oximeter (74DQA)

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EQUIVALENCE (Predicate Device)

The CAS 750E Series Monitor is equivalent to the following devices:

- CAS 750C Monitor (K050844);
- Welch Allyn Atlas Monitor (K022084).

DESCRIPTION

The CAS 750E Series Monitor is a multi-parameter patient monitor based on the exterior design and platform of the CAS 750C Vital Signs Monitor. The 750E features a capnograph equivalent to the Oridion Polaris 2004 End-Tidal C02 for the continuous non-invasive measurement and monitoring of carbon dioxide concentration of expired and inspired breath. Monitors in the series also have a choice of MasimoSET® or Nellcor® OxiMAX® Sp02 technology, and a CAS MAXNIBP® noninvasive blood pressure monitor. In addition, the 750E will monitor ECG, heart rate, respiration rate and temperature.

All ten monitors in the 750E series have ECG, respiration and temperature, as one module. Eight of the ten have an additional second parameter consisting of a pulse oximeter with a choice to the customer of Masimo or Nellcor technology. Five of the ten monitors in the series feature non-invasive blood pressure. Blood pressure measurement is based on the CAS oscillometric technology. The fourth parameter, found in four of the ten monitors in the series is a capnograph to measure EtC02. With the exception of the ECG/Respiration/Temperature parameters, all others are identical to that which is found in the CAS 750C Series Monitor - (K050844). See the matrix below.

The 750E monitor is a rugged, portable and lightweight unit widely adaptable for many applications and mounting schemes. Used for spot-checking or continuous monitoring, its features include an easily replaceable Nickel Metal Hydride rechargeable battery pack, wireless infrared printer communication, and a backlit LCD display with both waveform and a numeric display.

The monitor and parameters:

Model(s)	Parameters (Variations)
750E-1 (750EM-1)	ECG, respiration and temperature, 100 - 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-2 (750EM-2)	ECG, respiration and temperature & NIBP, 100 - 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-2MS, (750EM-2MS)	ECG, respiration and temperature & Masimo $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).

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Model(s)	Parameters (Variations)
750E-2NL, (750EM-2NL)	ECG, respiration and temperature & Nellcor $Sp0_2$, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3MSC (750EM-3MSC)	ECG, respiration and temperature, Masimo Sp02, and EtC02, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3NLC (750EM-3NLC)	ECG, respiration and temperature, Nellcor Sp02, and EtC02, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3MS (750EM-3MS)	ECG, respiration and temperature, Masimo $Sp0_2$, & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-3NL (750EM-3NL)	ECG, respiration and temperature, Nellcor $Sp0_2$, & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-4MS (750EM-4MS)	ECG, respiration and temperature, Masimo $Sp0_2$, EtC02 & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).
750E-4NL (750EM-4NL)	ECG, respiration and temperature, Nellcor $Sp0_2$, EtC02 & NIBP, 100 – 240VAC 50/60Hz, AC power supply and battery; (same but with 12VDC power input and battery, Mounting clamp included).

750E Series Indications for Use

The 750E Patient Monitor is intended to continuously monitor a patients ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (Sp02), respiration rate, temperature and end tidal carbon dioxide (C02). The monitor is designed as a bedside/portable monitor and is intended for use on adult, pediatric and neonatal patients in the care of health care professionals.

Comparison of Technological Characteristics

The 750E monitor is derived from the CAS 750C (K050844) with regard to form factor and general overall look. A number of identical components are found in both products, most especially the End Tidal C02 (EtC02), choice of pulse oximeters; Masimo SET® or Nellcor® OxiMax® and non-invasive blood pressure MAXNIBP® parameter. The 750E series adds the new parameter(s) ECG, Impedance Respiration and temperature (skin surface). The predicate for this portion of the device is the Atlas 220 monitor from Welch Allyn (K022084). CAS makes use of the OEM modules, and appropriate accessories in accordance with the manufacturer's recommendation with no modifications

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Nonclinical Performance Testing to Show Substantial Equivalence

The model 750E will be tested in accordance with the following standards as per CAS Product Performance Specifications prior to release to market. The following non-clinical tests will be performed:

- UL60601-1 (w/ CSA 22.2 No. 60601-1) Safety testing for use of the UL Classified mark;
- IEC60601-1 Safety of Medical Electrical Equipment;
- EN60601-1-2: 2001 Safety of Medical Electrical Equipment with regard to EMC Emissions and EMC Immunity;
- IEC60601-2-30 Safety of Medical Electrical Equipment – Particular Requirements for Automatic Cycling Indirect blood Pressure Monitoring Equipment;
- IEC60601-2-49 Safety of Medical Electrical Equipment – Particular Requirements for the Safety of multifunctional Patient Monitoring Equipment;
- EN 865 Pulse Oximeters – Particular Requirements;
- EN 864 Capnometers for use with Humans – Particular Requirements;
- ANSI/AAMI SP10: 2002 – Electric or Automated Sphygmomanometers (accuracy, performance and environmental);
- NIBP Monitor Guidance V1.0 March 1997;
- IEC68-2-6, -27 and - 34 Mechanical Shock and Vibration;

Clinical Testing to Show Substantial Equivalence

The OEM parameter suppliers (EtC02 an Sp02) have demonstrated successful clinical performance within their own premarket submissions. Those modules are unchanged for inclusion within the model 750E.

The NIBP parameter has been clinically demonstrated to meet the clinical accuracy of AAMI SP10: 2002.

The ECG, impedance respiration and temperature portion of the monitor have been validated for performance through in-house validation plans.

Conclusions Drawn from Clinical and Nonclinical Testing

With the substantial testing of a non-clinical and clinical nature, it is the conclusion that the 750E is substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

CAS Medical System, Inc.
c/o Mr. Ron Jeffrey
Director, Regulator Affairs
44 East Industrial Rd.
Branford, CT 06405

Re: K051896
Trade Name: Model 750E Series Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI, DRT, BZQ, FLL
Dated: November 23, 2005
Received: November 25, 2005

Dear Mr. Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: 750E Series monitor

Indications for Use: The 750E Patient Monitor is intended to continuously monitor a patients ECG, heart rate, non-invasive blood pressure (NIBP), functional arterial oxygen saturation (Sp02), respiration rate, temperature and end tidal carbon dioxide (C02). The monitor is designed as a bedside/portable monitor and is intended for use on adult, pediatric and neonatal patients in the care of health care professionals.

Prescription Use __x___ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051896